

## REMARKS

Claims 1-43 were pending in this application. Claims 25-27 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 2, 4, 8-10, 12, 13, 16, 18, 20, 21, 23, 24, 28, and 33-37 were rejected under 35 U.S.C. § 102(b) as being anticipated by Muller (U.S. Patent No. 4,506,682; hereafter “Muller”). Claims 1, 3, 11, 29, 30-33, and 35 were rejected under 35 U.S.C. § 102(b) as being anticipated by White (U.S. Patent No. 6,048,404; hereafter “White”). Claims 33, 35, and 37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Muller. Claims 5-7 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over White. Claims 29 and 30 were objected to for failing to further limit the base claim and for containing a typographical error, respectively. Claims 14, 15, 17, 19, and 38-43 were objected to as being dependent upon a rejected based claim. Applicants address each of these rejections and objections below.

### Claim Amendments

This Reply amends claims 1-5 and 25-30 and adds new claims 44-57. Claims 1-5 have been amended to recite a specific list of subcritical fluids and/or conditions that can be used for the extraction. Claims 25-27 have been amended to specify that the flavor or aroma compounds removed in step (b) are deposited in the tobacco “after step (c).” Claim 28 has been amended to depend from any one of claims 1-5 and to specify that the subcritical fluid is “carbon dioxide at 0-24°C and 1000-2200 psi, and the tobacco of step (a) has a moisture content of at least 30%.” Claim 29 has been amended to specify that the “subcritical fluid is ethane at 0-30°C and 500-2000 psi or Freon 22 at 0-50°C and 100-2000 psi, and the tobacco of step (a) has a moisture content of at least 20%.”

New claims 44 and 45 are directed to the method of claim 1, wherein the “subcritical fluid is carbon dioxide at 0-24°C and 1000-2200 psi, propane at 0-50°C and 100-2000 psi, or butane” and the tobacco of step (a) has a moisture content of “at least

40%” and “at least 50%,” respectively. New claims 46 and 47 are directed to the method of claim 1, wherein the “subcritical fluid is ethane at 0-30°C and 500-2000 psi or Freon 22 at 0-50°C and 100-2000 psi” and the tobacco of step (a) has a moisture content of “at least 30%” and “at least 40%,” respectively. New claims 48-57 correspond to the subject matter of previously pending claims 14, 15, 17, 19, and 38-43.

Support for the claim amendments is found in previously pending claims 14, 15, 17, 19, and 38-43 and at page 3, lines 26-28; page 4, lines 22-25; page 8, lines 14-16; page 9, lines 7-9; page 10, lines 4-5; and page 11, lines 5-8 of the specification. No new matter has been added by the present amendment. Applicants reserve the right to pursue any cancelled subject matter in this or in a continuing application.

### **Claim Objections**

Claim 29 was objected to under 37 C.F.R. § 1.75(c) as being in “improper dependent form for failing to further limit the subject matter of a previous claim” (Office Action, page 2). Claim 29 has been amended to specify that the “subcritical fluid is ethane at 0-30°C and 500-2000 psi or Freon 22 at 0-50°C and 100-2000 psi, and the tobacco of step (a) has a moisture content of at least 20%.” As amended, claim 29 is now clearly directed to a species encompassed by the genus of claim 1. The objection to this claim should therefore be withdrawn.

Claim 30 is objected to for containing a typographical error. Since claim 30 has been amended to correct this error, this objection may now be withdrawn.

Claims 14, 15, 17, 19, and 38-43 are objected to as being dependent upon a rejected based claim. Applicants address the rejections of the base claims (i.e., claims 1, 2, 5, 11, 12, and 16) below. Applicants submit that, upon withdrawal of the rejections of claims 1, 2, 5, 11, 12, and 16, the objection of claims 14, 15, 17, 19, and 38-43 should be withdrawn.

### **Allowable Subject Matter**

The Office Action indicated that claims 14, 15, 17, 19, and 38-43 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. The subject matter of claims 14, 17, 19, and 38 has been rewritten into independent form as new claims 48 and 50-52. The subject matter of claims 15 and 39-43 has been rewritten as new claims 49 and 53-57, which all depend directly or indirectly from either new claim 48 or new claim 52. Since this subject matter has been indicated to be allowable by the Office and is no longer dependent on any rejected base claim, Applicants respectfully request that new claims 48-57 be allowed.

### **Rejections under 35 U.S.C. § 112, second paragraph**

Claims 25-27 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for “failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention” (Office Action, page 2). Specifically, the Office states that recitation of the phrase “said tobacco” in claims 25-27 “makes it unclear which tobacco is being referred” (Office Action, page 2). Claims 25-27 have been amended to specify that the tobacco is the “tobacco after step (c).” Thus the rejection of claims 25-27 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

### **Rejections under 35 U.S.C. § 102**

Claims 2, 4, 8-10, 12, 13, 16, 18, 20, 21, 23, 24, 28, and 33-37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Muller. Claims 1, 3, 11, 29, 30-33, and 35 are rejected under 35 U.S.C. § 102(b) as being anticipated by White. The Office asserts that Muller discloses the steps of “providing a vessel 4 comprising tobacco..., contacting the tobacco with sub-critical carbon dioxide..., and removing the fluid from the vessel to extract a component (tobacco aroma oil) from the tobacco...” (Office Action, page 3).

The Office further asserts that since Muller “contacts the tobacco under...substantially the same sub-critical conditions...as disclosed by applicant...it would be inherent that the claimed specific components would also be extract[ed] from Muller’s treated tobacco” (Office Action, page 3). In addition, the Office states that White discloses contacting tobacco with carbon dioxide “at sub-critical conditions...” and that “it would be inherent that the tobacco will have a reduced constituent as claimed because White contacts the tobacco under...substantially the same sub-critical conditions as claimed by applicant” (Office Action, page 4). Applicants respectfully disagree.

Independent claims 1-5, as amended, are directed to methods of reducing the amount of a constituent in tobacco that require the step of contacting the tobacco with a subcritical fluid, “wherein said subcritical fluid is carbon dioxide at 0-24°C and 1000-2200 psi and the tobacco of step (a) has a moisture content of at least 30%; said subcritical fluid is ethane at 0-30°C and 500-2000 psi; said subcritical fluid is propane at 0-50°C and 100-2000 psi and the tobacco of step (a) has a moisture content of at least 30%; said subcritical fluid is Freon 22 at 0-50°C and 100-2000 psi; or said subcritical fluid is butane and the tobacco of step (a) has a moisture content of at least 30%.” Neither Muller nor White discloses the extraction of tobacco using the subcritical fluids and/or conditions specified in the amended claims. These references thus fail to anticipate the amended claims.

Muller generally describes the primary extraction of tobacco using “benzene, toluene, methanol, ethanol, n-propanol, methylethyl acetate, diethyl ether, acetone, n-propane, n-hexane, cyclohexane, petroleum ether, dichloromethane or trichloromethane.... [or] CO<sub>2</sub>...” (column 2, lines 42-50). Muller states that the primary extraction with an organic solvent (e.g., n-propane) should be carried out under “normal pressure conditions” (column 3, lines 8-9), normal atmospheric pressure being 15 psi, but fails to teach performing the organic solvent extraction using subcritical conditions.

Muller teaches that primary extraction with carbon dioxide should be performed using conditions “identical to those which are indicated...[for] the (one-stage) secondary extraction...” (column 3, lines 9-16). Muller generally describes subcritical conditions (i.e., “subcritical pressure and subcritical temperature”) of 5-25°C and 25-70 bar (corresponding to 362-1015 psi) (column 4, lines 9-12), and teaches that, for CO<sub>2</sub> secondary extraction, conditions of 15-30°C and 45-65 bar (corresponding to 653-942 psi) and 20-25°C and 50-55 bar (corresponding to 725-797 psi) are preferred (column 4, lines 48-53). Muller, however, fails to teach that the subcritical carbon dioxide extraction should be performed using tobacco with a moisture content of **at least 30%**, as specified in the amended claims. Muller only describes the extraction of tobacco having a moisture content of **under 10%**. For example, Muller describes the extraction of tobacco having a water content of 6.5%, 8.0%, 7%, and 7.2% in Examples 1-4, respectively. Muller further states that the method “does not add or use moisture in any process stage...” (column 5, lines 59-61). Muller also fails to teach the other subcritical fluids and conditions required by the amended claims, i.e., subcritical ethane at 0-30°C and 500-2000 psi; subcritical Freon 22 at 0-50°C and 100-2000 psi; or subcritical butane.

In contrast to Muller, the present application discloses that the subcritical fluids/conditions recited in the amended claims result in the removal of polycyclic aromatic hydrocarbons, the selective removal of secondary alkaloids relative to primary alkaloids, and the selective removal of polycyclic aromatic hydrocarbons relative to primary alkaloids. In addition, the application discloses that variations in the moisture content of tobacco during subcritical extraction affect the amount and selectivity of constituent removal from the tobacco. For example, data in the specification demonstrate that the moisture content of the tobacco affects the amount of secondary alkaloid removed and the selectivity of the removal of secondary alkaloids compared to primary alkaloids (see Table 1, page 8 of the specification; compare data from samples 1 and 2 performed

under identical temperature and pressure conditions, but having a moisture content of 15% and 30%, respectively). Since Muller uses different subcritical fluids and/or conditions than those recited in the amended claims, it does not expressly or inherently disclose the methods of amended claims 1-5. The § 102 rejection based on Muller should, therefore, be withdrawn.

Nor is the claimed invention anticipated by White. White generally describes subjecting tobacco material to high temperatures “above about 100°C...” (column 3, lines 48-51; emphasis added) and a pressure of “about 100 to 1000 psig, more preferably about 200 to 500 psig, with an inert gas such as nitrogen or carbon dioxide, a hydrocarbon gas such as methane, ethane, or butane...” (column 3, lines 53-58). White also describes that the liquid content of the tobacco “should be less than about 20% of the total weight” (column 5, lines 8-10; emphasis added), and is “preferably 15 wt% moisture or less...” (column 2, lines 62-67). As White only describes the use of temperatures above 100°C and the use of tobacco having a moisture content of less than 20%, White also fails to describe the treatment of tobacco using the subcritical fluids and/or conditions required by the present claims.

Like Muller, White fails to describe the advantages of extraction using the presently claimed subcritical fluids and/or conditions or the advantages of performing subcritical extraction using tobacco with a moisture content of greater than 30%. As White does not disclose the specific subcritical fluids and/or conditions recited in the amended claims, it does not expressly or inherently describe a tobacco produced by the methods of presently pending claims 1-5. The § 102 rejection based on White should also be withdrawn.

### **Rejections under 35 U.S.C. § 103**

Claims 33, 35, and 37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Muller. Claims 5-7 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over White. The Office states that “the claimed product would have been obvious to a person of ordinary skill in the art because [Muller] substantially mirrors the claimed process steps,” the “claimed process only differs from [Muller] in that it recites a specific moisture content of the treated tobacco,” and the water content limitation “does not further add structural limitations distinct to [Muller’s] tobacco because it would be expected to have the claimed reduction of constituent tobacco...” (Office Action, page 5). The Office further states that, in view of White, “it would have been obvious to a person of ordinary skill in the art to have recycled the gas in order to reduce cost” (Office Action, page 6).

As noted above, neither Muller nor White describe the specific subcritical conditions now required by the amended claims, namely, subcritical carbon dioxide at 0-24°C and 1000-2200 psi with a tobacco moisture content of at least 30%; subcritical ethane at 0-30°C and 500-2000 psi; subcritical propane at 0-50°C and 100-2000 psi with a tobacco moisture content of at least 30%; subcritical Freon 22 at 0-50°C and 100-2000 psi; or subcritical butane with a tobacco moisture content of at least 30%.

Although Muller does disclose subcritical carbon dioxide extraction, Muller fails to teach or suggest subcritical carbon dioxide extraction at 0-24°C and 1000-2200 psi using tobacco having a moisture content of at least 30%. Muller also fails to describe subcritical propane extraction at 0-50°C and 100-2000 psi, or the use of any of the other subcritical fluids and/or conditions specified in the amended claims. White only describes the use of temperatures above 100°C and fails to describe the use of tobacco having a moisture content of at least 30%, and therefore, also fails to teach or suggest the subcritical fluids and/or conditions specified in the amended claims.

Muller and White also fail to teach or suggest the beneficial effects afforded by the presently claimed subcritical fluids/conditions. As noted above, Applicants have discovered that the subcritical fluids/conditions specified in the amended claims result in the removal of polycyclic aromatic hydrocarbons, the selective removal of secondary alkaloids relative to primary alkaloids, and the selective removal of polycyclic aromatic hydrocarbons relative to primary alkaloids (see, e.g., Tables 1-3 demonstrating the selective removal of secondary alkaloids relative to primary alkaloids using subcritical carbon dioxide, Freon 22, and propane, respectively; and Table 4 demonstrating the removal of polycyclic aromatic hydrocarbons and the selective removal of polycyclic aromatic hydrocarbons relative to primary alkaloids using subcritical propane).

Contrary to the assertion in the Office Action that the moisture content of the tobacco would not affect the results of the extraction process, Applicants have further demonstrated in the present specification that variations in the moisture content of tobacco during subcritical extraction affect the amounts of the constituents removed and the selectivity of the removal of the constituents compared to primary alkaloids. For example, data in the specification demonstrate that the moisture content of the tobacco has a significant affect on the amount of secondary alkaloids extracted and the selective removal of secondary alkaloids compared to primary alkaloids (see Table 1, page 8 of the specification; compare data from samples 1 and 2 performed under identical temperature and pressure conditions, but having a moisture content of 15% and 30%, respectively). Specifically, Applicants have discovered that extraction of secondary alkaloids and selective extraction of secondary alkaloids compared to primary alkaloids using subcritical carbon dioxide is best achieved using tobacco with a moisture content of **at least 30%**.



For these reasons, Applicants submit that it would not have been obvious to one skilled in the art to arrive at the subcritical fluids and/or conditions specified in the amended claims using the teachings of Muller and/or White. The rejections under 35 U.S.C. § 103 should therefore be withdrawn.

### CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is hereby respectfully requested.

Enclosed is a Petition to extend the period for replying to the final Office Action for one month, to and including February 5, 2010, and payment of the required extension fee.

Transmitted herewith is payment of \$780.00 required under 37 C.F.R. § 1.16(i) for a total of 15 additional claims and payment of \$880.00 required under 37 C.F.R. § 1.16(h) for a total of 4 additional independent claims.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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